UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, the PEOPLE OF THE STATE OF NEW YORK and the COUNTY OF ONONDAGA, ex. rel. PAUL BLUNDELL, Relator,

Plaintiffs,

vs.

5:09-CV-00710 (NAM/DEP)

DIALYSIS CLINIC, INC.,

Defendant.

APPEARANCES: **OF COUNSEL:**

OFFICE OF PETER HENNER
P.O. Box 326
Clarksville, New York 12041-0326
Attorney for Plaintiff Blundell

Peter Henner, Esq.

CARTER, CONBOY, CASE, BLACKMORE, MALONEY & LAIRD, P.C.
20 Corporate Woods Boulevard
Albany, New York 12211
Attorneys for Defendant

Michael J. Murphy, Esq.

BUCHANAN, INGERSOLL & ROONEY, PC
Two Liberty Place
50 S. 16th Street, Suite 3200
Philadelphia, Pennsylvania 19102
Attorneys for Defendant

James M. Becker, Esq.

Norman A. Mordue, Chief U.S. District Judge:

MEMORANDUM DECISION AND ORDER

INTRODUCTION

On June 22, 2009, plaintiff Paul Blundell filed this *qui tam* action under seal in accordance with the provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*. as a

relator on behalf of the United States of America, the State of New York and the County of Onondaga. On July 10, 2009, plaintiff filed an amended complaint under seal. Plaintiff asserted claims based upon the federal FCA and the New York State False Claims Act, §§ 188-194 of the New York State Finance Law. On February 24, 2010, the United States filed its Notice of Election to Decline Intervention and on the same day, the complaint was unsealed. On April 21, 2010, plaintiff served defendant. Presently before the Court are three motions: (1) defendant's motion pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure to dismiss the amended complaint for failure to plead fraud with particularity and failure to state a cause of action (Dkt. No. 27); (2) plaintiff's motion for leave to file a second amended complaint (Dkt. No. 30); and (3) defendant's motion pursuant to Rule 12(b)(1) to dismiss the second amended complaint for lack of subject matter jurisdiction. (Dkt. No. 34).

BACKGROUND[1]

In support of the claims herein, plaintiff makes the following factual and legal averments: Dialysis Clinic, Inc. ("DCI" or defendant) is a dialysis treatment center with over 200 outpatient dialysis facilities in the United States. Plaintiff, a resident of Liverpool, New York, was employed at DCI's University Dialysis Center ("UDC") from August 2007 until October 2008 as a staff nurse, team leader and charge nurse. Dialysis is a method of treating End Stage Renal Disease ("ESRD").[2] The federal Medicare program provides coverage for most individuals who are diagnosed with ESRD and organizations that provide these services are eligible for Medicare

[1] The facts recited herein are drawn from the amended complaint, plaintiff's affidavit submitted in opposition to defendant's motion and plaintiff's supporting documents. Defendant moves for dismissal, therefore, the Court assumes the facts asserted in the amended complaint to be true for the purposes of the motions.

[2] Plaintiff defines dialysis as a filtration system that replaces the function of the kidneys with a chemical solution and removes waste products and excess fluids from the blood stream. Dorland's defines dialysis as, "the removal of certain elements from the blood by virtue of the difference in the rates of their diffusion through a semipermeable membrane". *Dorland's Illustrated Medical Dictionary*, 515 (31st ed. 2007).

reimbursement. During plaintiff's employment with defendant, he questioned DCI's documentation of dialysis treatment which implicated billing issues for Medicare, Medicaid and Veterans' Administration patients. Plaintiff was not directly involved in the billing procedures and did not have access to the bills that were submitted for government reimbursement.

In 2008, the New York State Office of the Medicaid Inspector General ("OMIG")[3] conducted an audit and reviewed payments made from the New York State Medicaid Program to defendant from January 1, 2004 through December 31, 2005. On October 23, 2008, the OMIG issued a "Final Audit Report". The report was publicly available on the internet after October 23, 2008. The purpose of the report was described as follows:

> This review consisted of a random sample of 200 services with Medicaid payments of $26,940.54. The purpose of the audit was to ensure that: Medicaid reimbursable services were rendered for the dates billed; appropriate rate or procedure codes were billed for services rendered; patient related records contained the documentation required by the regulations; and claims for payment were submitted in accordance with Department regulations and the Provider Manuals for Clinics.

The Audit Report contained four "Detailed Findings" set forth in pertinent part as follows:

- <u>missing documentation</u>

  In 12 instances pertaining to 8 patients, the kidney dialysis services were not documented. Of these services, we found 5 instances where the written order for services was missing and 5 instances where the written order lacked the required signature. In 2 instances the Hemodialysis Flowsheet was missing.

- <u>service delivery documents not signed by a licensed health professional</u>

[3] The Audit Report describes OMIG's function as: "The OMIG conducts audits and reviews of various providers of Medicaid reimbursable services, equipment and supplies. These audits and reviews are directed at ensuring provider compliance with applicable laws, regulations, rules and policies of the Medicaid program . . ."

> In 11 instances pertaining to 7 patients, the signature of a licensed health care professional, attesting to the delivery of the treatment service, was lacking on the Hemodialysis Flowsheet.

- threshold visit billed for incomplete treatment session

  In 4 instances relating to 4 patients, a threshold visit was incorrectly billed for hemodialysis sessions terminated before the treatment was completed.

- No EOB for Medicare covered services

  In 4 instances pertaining to 2 patients, no Explanation of Medical Benefits was found for a Medicare eligible patient.

As a result of the aforementioned, the audit revealed sample overpayments in the amount of $4,171.20 resulting in a "mean per unit point" estimate of $160,508.00.[4] The report provided defendant with repayment options and further indicated:

> Failure to arrange payment within 20 days of the issuance of this report will result in initiation of a 10% withhold of your Medicaid billings to recover the lower confidence limit amount of $113,499.00. If the repayment term exceeds ninety (90) days, repayment interest will be charged as stated in the previous paragraph.

Plaintiff's employment with DCI ended two weeks before the Audit Report was issued and plaintiff was not aware of the audit report until after the report was posted on the Internet.

In the amended complaint, plaintiff alleges that DCI failed to comply with the New York State Public Health Law Regulations governing the operation of dialysis facilities and Title 42 of the Code of Federal Regulations, Public Health, Part 405, Subpart U-Conditions of Coverage of Suppliers of End-State Renal Disease (ESRD) Services.[5] (Am. Compl., ¶ 18). Plaintiff claims

[4] The OIG employed the statistical sampling methodology set forth in 18 NYCRR § 519.18(g) which allows for, "the extrapolation based upon an audit utilizing a statistical sampling".

[5] Plaintiff alleges that 42 CFR Part 494 was adopted in April 15, 2008 and replaced 42 CFR § 405 and added several new sections. (Am. Compl., ¶ 21).

that 42 C.F.R. § 494 requires compliance with standards, "to protect dialysis patients' health and safety and to ensure that quality care is furnished to all patients in Medicare approved dialysis facilities." (*Id.* at ¶ 22). Plaintiff contends that DCI violated those procedures and regulatory requirements resulting in compromised patient care. Thus, defendant's submission of claims for payment to Medicare, Medicaid and the Veterans' Administration were fraudulent as they were based upon "false certifications". Specifically, plaintiff alleges that defendant violated the standards and regulatory requirements in the following respects: (1) by failing to provide adequate staffing; (2) using unqualified personnel; (3) falsifying records; (4) permitting Personal Care Technicians ("PCT") to perform nursing functions; (5) permitting PCTs to administer Heparin; (6) permitting an Licensed Practical Nurse ("LPN") or PCT to assess a patient's condition; (7) allowing a PCT to verify prescription medication; (8) allowing home dialysis treatment to fail due to the lack of appropriate supervision; (9) failing to employ the appropriate techniques to prevent cross-contamination; (10) failing to provide comfortable temperatures within the facility; (11) failing to adequately survey or monitor patients receiving dialysis services; (12) failing to adequately train employees in all aspects of emergency preparedness; (13) failing to provide patients with information and to ensure that they understood their rights; (14) falsifying initial comprehensive assessment records; (15) failing to allow a register nurse to participate in interdisciplinary meetings; and (16) appointing nurses with inadequate experience.

Plaintiff claims that DCI defrauded the United States, State of New York and Onondaga County when it submitted Medicare claims and falsely certified that it was in compliance with applicable state and federal regulations pertaining to dialysis services. Plaintiff alleges four causes of action against defendant including Medicaid fraud, Medicare fraud, fraud against the

Veterans Administration and Medicaid fraud against the State of New York and Onondaga County. Plaintiff alleges:

> Because DCI's claims for payment are based upon false certification that the UDC facility is in compliance with the applicable rules and regulations and of generally accepted practices for quality of care, DCI's claims for payment are false claims within the meaning of FCA. (Am. Compl., ¶ 131).
>
> . . . services rendered at UDC were of low quality care and constituted a significant danger to patients undergoing dialysis treatment. (*Id.* at ¶ 132).
>
> DCI knew, or should have know, that the United States of America would not pay for such services under the Medicaid program, if it had been aware of the poor quality of treatment and of the risks to patients. (*Id.* at ¶ 133).
>
> [], the UDC facility owned and operated by DCI has failed to meet a number of the standards for Medicare coverage set forth [in] Part 405 and in Part 494. (*Id.* at ¶ 144).
>
> Consequently, the claims for payment that had been submitted by DCI for services rendered at UDC represent reimbursement payments for services to which DCI was not entitled. (*Id.* at ¶ 145).
>
> DCI submitted claims for Medicare payments for services that were not rendered in compliance with the requirements of federal regulations pertaining to ESRD services. (*Id.* at ¶ 146).
>
> Upon information and belief, the Veterans Administration would not have paid DCI's claims, had it been aware of the violations of state and federal regulations, including violations of the Medicare regulations for ESRD treatment, the low quality of care provided at the UDC facility, and of the significant risks to patient health which were created by UDC practices and non-compliance with regulatory criteria. (*Id.* at ¶ 161).
>
> Upon information and belief, DCI's receipt of funds for Medicaid patients from New York State and Onondaga County constitutes a violation of 189 of the New York State Finance Law. (*Id.* at ¶ 173).

DISCUSSION

On April 30, 2010, defendant filed a motion to dismiss pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6). (Dkt. No. 27). Plaintiff opposed the motion and filed a cross-motion for leave to file a second amended complaint. (Dkt. No. 30). In response to plaintiff's cross-motion, defendant filed a second motion to dismiss the second amended complaint for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1). (Dkt. No. 34).

I. FALSE CLAIMS ACT

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, empowers the United States, or private citizens on behalf of the United States, to recover treble damages from those who knowingly make false claims for money or property upon the United States, or cause to be made, or who submit false information in support of such claims. *U.S. ex rel. Dick v. Long Island Lighting Co.*, 912 F.2d 13, 16 (2d Cir. 1990). The issue examined under the FCA is whether defendant presented a "false" or "fraudulent claim" to the government. *Johnson v. The Univ. of Rochester Med. Ctr.*, 686 F.Supp2d 259, 265 (W.D.N.Y. 2010) (citations omitted). Section 3729 provides, in pertinent part:

> (a) Liability for certain acts.
>
> (1) Any person who - -
>
> > (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> > (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.

31 U.S.C. § 3729(a).

Under the *qui tam* provisions of the FCA, private persons may bring civil actions for violations of § 3729(a). *U.S. ex rel. Woods v. Empire Blue Cross and Blue Shield*, 2002 WL 1905899, at *4 (S.D.N.Y. 2002). These suits are brought in the name of the Government and the

plaintiff, or "relator," must provide the Government with a copy of the complaint and written disclosure of all material evidence and information. *Id.* (citing 31 U.S.C. § 3730(b)(2)). The complaint remains under seal for at least 60 days; during that time the Government decides to either: a) proceed with the action; or b) notify the court that it declines to take over the action, leaving the relator with the right to conduct the action. *Id.* (citing 31 U.S.C. § 3730(4)). If the prosecution is successful, the relator is entitled to receive some of the proceeds. *Id.* (citing 31 U.S.C. § 3730(d)).

II. PROPOSED SECOND AMENDED COMPLAINT

Upon receipt of defendant's motion to dismiss for failure to properly plead an action for fraud and/or failure to state a cause of action, plaintiff moved for leave to file a second amended complaint and in support, submitted a proposed second amended complaint as an exhibit to the motion. "Although leave to amend a pleading under the Federal Rules of Civil Procedure 'shall be freely given when justice so requires,' such leave will be denied when an amendment is offered in bad faith, would cause undue delay or prejudice, or would be futile." *Leonelli v. Pennwalt Corp.*, 887 F.2d 1195, 1198 (2d Cir.1989) (citing *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

Plaintiff submitted a proposed second amended complaint in an attempt to address the deficiencies in the amended complaint. Plaintiff has not asserted new causes of action and, in fact, defendant has already addressed the merits of the second amended complaint. Upon receipt of plaintiff's proposed second amended complaint, defendant submitted a Reply Memorandum and addressed the additional facts and allegations in the second amended complaint. Moreover, in further response to plaintiff's cross motion and proposed second amended complaint, defendant filed a second motion seeking an order dismissing the second amended complaint pursuant to Fed. R. Civ. P. 12(b)(1) for lack of jurisdiction. There has been no undue delay and no prejudice

as defendant has not filed an answer. In this case, no undue prejudice will result in permitting plaintiff to file the second amended complaint. *See Volovnik v. Benzel-Busch Motor Car Corp.*, 2010 WL 3629819, at *3 (S.D.N.Y.2010) (proposed amendment in response to motion to dismiss was not offered in bad faith or for a dilatory purpose); *see also Melendez v. Int'l Serv. Sys., Inc.*, 1999 WL 187071, at *1 (S.D.N.Y. 1999); *see also Baer v. Interim Occupational Health, Inc.*, 2000 WL 207163, at *3 (W.D.N.Y. 2000) ("to facilitate the orderly and prompt resolution of the pending motions and given that no defendant oppose[d] the cross-motion for leave to amend the complaint", the court granted the cross-motion for leave to amend, deemed the "Proposed Amended Complaint" filed and deemed the motions to dismiss to pertain to the Amended Complaint). Therefore, the Court will accept the second amended complaint and deem it filed. To promote judicial efficiency, the Court will now address defendant's motions to dismiss for lack of jurisdiction, failure to plead with particularity and failure to state a claim in relation to the allegations in the second amended complaint.

III. SUBJECT MATTER JURISDICTION

A. Legal Standard

Defendant moves for dismissal pursuant to Fed. R. Civ. P. 12(b)(1) for lack of jurisdiction. In contemplating a motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), the Court must "accept as true all material factual allegations in the complaint[,]" *Atl. Mut. Ins. Co. v. Balfour MacLaine Int'l Ltd.*, 968 F.2d 196, 198 (2d Cir. 1992) (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)), though "argumentative inferences favorable to the party asserting jurisdiction should not be drawn." *Id.* (citing *Norton v. Larney*, 266 U.S. 511, 515 (1925)). The Court may consider evidence outside the pleadings, e.g., affidavit(s), documents or otherwise competent evidence. *See Kamen v. Am. Tel. & Tel. Co.*, 791 F.2d 1006,

1011 (2d Cir. 1986); *Antares Aircraft v. Fed. Rep. of Nigeria*, 948 F.2d 90, 96 (2d Cir. 1991). As the party "seeking to invoke the subject matter jurisdiction of the district court", plaintiff bears the burden of demonstrating that there is subject matter jurisdiction in this case by a preponderance of the evidence. *Scelsa v. City Univ. of New York*, 76 F.3d 37, 40 (2d Cir. 1996); *Malik v. Meissner*, 82 F.3d 560, 562 (2d Cir. 1996).

B. Section 3730(e)(4) and Jurisdiction

In cases of this nature, jurisdiction is limited by Section 3730(e)(4) which, "is intended to bar 'parasitic lawsuits' based upon publicly disclosed information in which would-be relators 'seek remuneration although they contributed nothing to the exposure of the fraud'". *U.S. ex. rel. Kreindler & Kreindler v. United Tech. Corp.*, 985 F.2d 1148, 1157 (2d Cir. 1993). The relevant portions of section 3730 of the FCA provide, in pertinent part:

> Certain actions barred - -
>
> (4)(A) No court shall have jurisdiction over an action under [the FCA] based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who (2) has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

U.S. v. ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 103 (2d Cir. 2010) (citing 31 U.S.C. §§ 3730(e)(4)(A), (4)(B)).[6]

[6] In *Kirk*, the Second Circuit addressed the applicability of the recent amendment of this provision:

> This provision was recently amended to specify that in order for the jurisdictional bar to apply,

On a motion to dismiss for lack of jurisdiction, the Court must engage in a two-part analysis: (1) whether the information on which the allegation of fraud rests, was a "public disclosure" through one of the sources enumerated in the statute; and (2) whether the relator's allegations are based upon "allegations or transactions" disclosed to the public. *See U.S. ex. rel. Mikes v. Straus*, 931 F.Supp. 248, 259 (S.D.N.Y. 1996); *see also Kirk*, 601 F.3d at 103. If the aforementioned factors are established, a *qui tam* plaintiff may avoid dismissal by establishing that he was an "original source" with "direct and independent knowledge". *Kirk*, 601 F.3d at 103. To qualify as an "original source", the plaintiff must have: (1) direct and independent knowledge of the information on which the allegations are based; (2) voluntarily provided such information to the government prior to filing suit; and (3) directly or indirectly been a source to the entity that publicly disclosed the allegations on which the suit is based. *U.S. v. New York Med. Coll.*, 252 F.3d 118, 120 (2d Cir. 2001).

1. Public Disclosure

"In order for the FCA's jurisdictional bar to apply there must be 'public disclosure' of the information on which the allegation of fraud rests, and this 'public disclosure' must occur through one of the sources enumerated in the statute." *Kirk*, 601 F.3d at 103 (citation omitted). Here, plaintiff concedes that the Audit Report has been publicly disclosed within the meaning of the

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> "substantially the same allegations or transactions" must be publicly disclosed in a federal criminal, civil, or administrative hearing, a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation, or by the news media. Patient Protection and Affordable Care Act, Pub.L. 111-148, § 10104(j)(2), 124 Stat. 119 (2010). Because this amendment was not made retroactive, *see Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S.Ct. 1396, 1400 n. 1 (2010), we do not address the new statutory language here. Throughout this opinion, we will use the present tense to refer to the version of the statute that applies in this case.

Kirk, 601 F.3d at 104, n.4.

statute. (Dkt. No. 36, p. 9). Even if plaintiff had not conceded this point, the Court takes judicial notice of the fact that OIG audits are included in the list of sources in § 3730(e)(4). *See U.S. v. Sodexho, Inc.*, 2009 WL 579380, at *8 (E.D. Pa. 2009).

2. "Based Upon"

Circuit courts are divided over the meaning of the phrase "based upon" as it is used in the FCA. *U.S. ex rel. Ondis v. City of Woonscoket*, 587 F.3d 49, 57 (1st Cir. 2009); *see also Glaser v. Wound Care Consulants*, 570 F.3d 907, 914 (7th Cir. 2009). The Second Circuit follows the majority view and has repeatedly held that the relator's claim is "based upon" the public disclosure if the allegations in the complaint are "substantially similar" to the publicly disclosed information. *U.S. ex. rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992); *Dick*, 912 F.2d at 18 ("if the information on which a *qui tam* suit is based is in the public domain, and the *qui tam* plaintiff was not a source of that information, then the suit is barred"); *see also Woods*, 2002 WL 1905899, at *5. The "substantially similar" rule controls even if the relator actually obtained his information from a difference source. *Doe*, 960 F.2d at 324.

On a motion to dismiss, the court should examine whether substantial identity exists between the publicly disclosed allegations and the *qui tam* complaint. *See also U.S. ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 514 (6th Cir. 2009). However, the Act bars suits based on publicly disclosed "allegations or transactions", not information. *Kirk*, 601 F.3d at 103 (citing *U.S. ex Rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, (C.A.D.C. 1994) (holding that "[t]he language employed in § 3730(e)(4)(A) suggests that Congress sought to prohibit *qui tam* actions only when either the allegation of fraud or the critical elements of the fraudulent transaction themselves were in the public domain")); *see also Mikes*, 931 F.Supp. at 258 (the distinction between allegations and information is crucial). The jurisdictional bar is applicable

only if the essential elements exposing the transaction as fraudulent are publicly disclosed. *U.S. ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512 (8th Cir. 1994). Therefore, the jurisdictional analysis must include an examination of whether the public disclosure included allegations or suggestions of fraud. *U.S. ex. rel. Winslow v. PepsiCo., Inc*., 2007 WL 1584197, at *6 (S.D.N.Y. 2007) (holding that a Request for Information that asked the defendant to submit samples was not sufficient to inform anyone of a fraud being imposed on the United States); *see also Cooper v. Blue Cross and Blue Shield of Fla., Inc*., 19 F.3d 562, 566 (11th Cir. 1994) (the public disclosure must contain some allegations of fraudulent conduct against the named defendant in the relator's litigation).

In this analysis, courts in this district have relied upon the formula set forth by the D.C. Circuit in *U.S. ex rel. Settlemire v. Dist. of Columbia*, 198 F.3d 913, 918 (D.C. Cir. 1999):

> [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

See Woods, 2002 WL 1905899, at *5 (citing *Settlemire*, 198 F.3d at 918).

Defendant argues that the jurisdictional bar warrants dismissal as the allegations in the second amended complaint are substantially similar to those previously disclosed in the OMIG Audit Report. Plaintiff disagrees and claims that the Audit Report disclosed "information", but not the "allegations or transactions" that are contained in plaintiff's second amended complaint. Plaintiff argues:

> The[] allegations are based upon my personal observations while I was employed at DCI; they are separate and apart from the information that the OMIG was able to learn through a review of the bills that were submitted. (Blundell Aff. at ¶ 6).

> There is nothing in the Audit Report that pertains to the actual treatment that was provided, and there is nothing in the Audit Report that relates to any of the issues regarding patient safety, violations of nursing practices and health and safety regulations in Medicare raised in this lawsuit. (*Id.* at ¶ 18).

Plaintiff annexed the Audit Report to the second amended complaint and incorporated the report by reference. Plaintiff specifically referred to the following aspects of the report:

> The office of the Medicaid Inspector General conducted an audit of the UDC facility for the period of January 1, 2004 through December 31, 2005. (Sec. Amd. Complt. at ¶ 49).
>
> The audit consisted of a random sample of 200 services. Based upon UDC's documented failure to comply with the provisions of § 405 and other regulatory requirements, the State determined that $4171.20 out of total Medicaid payments of $26,940.50, were payments that the State should not have made. (*Id*. at ¶ 53).
>
> Based upon the information contained in the audit report, Relator believes and alleges that UDC continued to submit claims for Medicaid reimbursement from 2006 to present. (*Id*. at ¶ 55).
>
> Relator alleges, as detailed below, a broad pattern of noncompliance with regulatory criteria. In addition to the non-compliance observed in the audit for the years 2004 and 2005, Relator describes a variety of incidents, representing both failures of documentation, and also serious issues pertaining to understaffing, failure to observe safety regulations, and other issues that critically compromised patient care. (*Id*. at ¶ 56).
>
> Upon information and belief, the audit was limited to review of documents that were prepared by DCI. Mr. Blundell alleges non-compliance with regulatory criteria based upon the actual performance of UDC and based upon his personal observations. (*Id*. at ¶ 57).
>
> The regulatory violations that are alleged by Mr. Blundell go far beyond the documentary shortcomings identified in the audit report. (*Id*. at ¶ 58).

Plaintiff alleges:

> UDC systematically violated proper procedures and regulatory requirements by failing to provide adequate staffing, permitting

> medication to be administered by unqualified personnel, permitting contamination of medications and supplies, falsifying medical treatment records, and improperly assessing patients. (Sec. Amd. Compl. ¶ 62).

Plaintiff further asserts that, "upon information and belief, many other incidents occurred". Plaintiff's second amended complaint contains four causes of action for fraud all relating to the "quality of care" provided at the facility.[7] Plaintiff alleges that DCI's claims for payment were false claims because they were based upon false certifications that the UDC facility was in compliance with the applicable rules and regulations and of generally accepted practices for quality of care.

The Court has reviewed the Audit Report and compared its findings with the allegations in plaintiff's second amended complaint. The public disclosure (Audit Report) involved defendant's billing practices and exposed overpayment based upon defendant's failure to comply with several sections of the New York State Department of Health Rules and Regulations. In the second amended complaint, plaintiff provided 16 different examples of instances where defendant allegedly violated patient safety conditions and therefore, "falsely certified" that it complied with Medicare's regulatory criteria. Moreover, plaintiff identified 13 patients (by their initials only, in the interest of confidentiality) who allegedly suffered from compromised patient care. In the Audit Report, the OMIG did not discuss or even address any alleged violations of medical procedures, risks to patients safety or any of the 16 examples of alleged violations of patient safety conditions or 13 alleged instances of compromised patient care as outlined by plaintiff in the second amended complaint. More importantly, the Audit Report does not suggest, infer or accuse defendants of fraud or any fraudulent conduct. At best, the Audit Report reveals errors

[7] The four causes of action asserted in the amended complaint were outlined in "Background", *supra*. The four causes of action asserted in the second amended complaint are identical.

and irregularities in defendant's billing practices. It does not accuse defendant of intentionally or fraudulently creating the discrepancies. *See Morgan ex rel. U.S. v. Sci. Applications Int'l. Corp.*, 2008 WL 2566747, at *5 (S.D.N.Y. 2008) (the report failed to point to any specific factual assertion that was allegedly falsely provided by the defendants).

In the report, the OMIG provided defendant with an opportunity to appeal the findings and options for repayment. Moreover, the report indicated that if defendant failed to arrange for re-payment, interest would be charged and future funds could be withheld. Nowhere in the report does the OMIG state, or even infer, that any action or inaction by defendant could, or would, compromise defendant's continued eligibility in the Medicaid program. The report is completely silent on the issue of termination.

The Court finds that plaintiff's allegations are distinct and separate theories of liability that are not set forth, "based upon", or even referenced, in the Audit Report. *Cf. Sodexho*, 2009 WL 579380, at *8 (the audit report described the exact theory and critical elements of fraud identified by the relator and it was irrelevant that the report did not discuss false certifications); *cf. U.S. v. New York City Health and Hosp. Corp.*, 2000 WL 1610802, at *4, n.2 (S.D.N.Y. 2000) (the plaintiff's complaint was based upon a state court action with a complaint that noted the fact that overpayments could constitute Medicare/Medicaid fraud). While the Audit Report and plaintiff's second amended complaint may overlap with respect to the "general subject matter", i.e. - Medicare/Medicaid billing, the allegations in the second amended complaint are not "substantially similar" to the publicly disclosed material. *See U.S. ex rel. Downey v. Corning*, Inc., 118 F.Supp.2d 1160 (D.N.M. 2000) (the public information did not contain allegations of fraud and did not contain the material elements of a fraud claim) *overruled on other grounds, U.S.*

ex rel. Sikkenga v. Regence Blue Cross Blue Shield of Utah, 472 F.3d 702 (10th Cir. 2006)). Thus, defendant's motion for dismissal pursuant to § 3730(e)(4) is denied.[8]

IV. MOTION TO DISMISS FOR FAILURE TO PLEAD WITH PARTICULARITY

A. Legal Standard

Defendant argues that plaintiff's claims of fraud are subject to dismissal as plaintiff failed to plead fraud with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. "In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other conditions of mind of a person may be averred generally." Fed.R.Civ.P. 9(b). Claims brought pursuant to the Federal Claims Act must comply with the heightened pleading requirements of Fed. R. Civ. P. 9(b). *Wood v. Applied Research Assocs., Inc*., 328 F. App'x 744, 747 (2d Cir. 2009). The purpose of Rule 9(b) is designed to provide a defendant with fair notice of a plaintiff's claim and to safeguard a defendant's reputation from "improvident charges of wrongdoing." *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991). To satisfy the pleading requirements of Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Id.* ("while Rule 9(b) permits scienter to be demonstrated by inference, this must not be mistaken for license to base claims of fraud on speculation and conclusory allegations. An ample factual basis must be supplied to support the charges.")) . Where a complaint fails to specify the time, place, speaker and content of the alleged misrepresentations, it will lack the particulars required by 9(b). *Wood*, 328 F.App'x at 748.

[8] As the jurisdictional bar does not apply, an examination of the "original source" issue is unnecessary.

There is a recognized exception to this rule where facts are peculiarly within the opposing party's knowledge; in such event the allegations must be accompanied by a statement of the facts upon which the plaintiff's belief is based. *See DiVittorio v. Equidyne Extractive Indus., Inc*., 822 F.2d 1242, 1247 (2d Cir. 1987); *Luce v. Edelstein*, 802 F.2d 49, 54, n. 1 (2d Cir.1986); *Segal*, 467 F.2d at 608. Even if plaintiff is entitled to a "relaxed rule of pleading", the claim must still allege a factual nexus between the improper conduct and the submission of a false claim to the government. *Johnson*, 686 F.Supp.2d at 266. As a general rule, Rule 9(b) pleadings cannot be based upon information and belief, *Segal v. Gordon*, 467 F.2d 602, 608 (2d Cir. 1972), however such a pleading is permitted if the complaint adduces specific facts supporting a strong inference of fraud. *Hinds County, Miss. v. Wachovia Bank N.A.*, 2010 WL 1837823, at *5 (S.D.N.Y. 2010) (citing *Wexner v. First Manhattan Co*, 902 F.2d 169,172 (2d Cir. 1990)). Standing alone, allegations of violations of federal regulations are insufficient to establish a claim under the FCA if plaintiff cannot identify, with any particularity, the actual false claims submitted by the defendant. *Johnson*, 686 F.Supp.2d at 265.

Here, defendant argues that the facts of the within action are similar to those presented in *U.S. ex rel. Smith v. New York Presbyterian Hosp.*, 2007 WL 2142312 (S.D.N.Y. 2010) and *Johnson v. The Univ. of Rochester Med. Ctr*, 686 F.Supp.2d 259 (W.D.N.Y. 2010). In *Smith*, the plaintiff, a doctor, claimed that the defendant perpetrated a scheme to defraud Medicare/Medicaid involving radiological studies which were not "medically necessary". *Smith*, 2007 WL 2142312, at *1. While the plaintiff's complaint "sketched out" the nature of the claim generally by stating the who, what, where, when and how, the Court found that it lacked sufficient detail about the theory of fraud or any specifics. *Id.* at *6. The complaint was deficient for the following reasons: (1) the plaintiff did not identify any employee who allegedly submitted any of the "thousands" of

fraudulent claims; (2) the plaintiff gave no details regarding the dates or amounts of the alleged fraudulent bills; and (3) the plaintiff did not allege that he or anyone else personally observed the submission of any fraudulent claims. *Id.* The Court dismissed the plaintiff's complaint concluding that his allegations failed to put the defendants on notice of the particular fraud alleged and to allow the case to go forward, "would improperly shift the burden of producing evidence from [the plaintiff] to [the defendant] and allow [the plaintiff] to use vague allegations of fraud to prompt a search for more specific evidence through protracted discovery". *Id.* at *7.

In *Johnson*, the complaint alleged a pattern of violations of hospital policy and Medicare/Medicaid regulations requiring the supervision of a teaching or attending physician. *Johnson*, 686 F.Supp.2d at 264. The plaintiff alleged that Medicare/Medicaid regulations made reimbursement contingent upon such supervision. *Id.* The complaint identified the general time period and frequency of the alleged failure to supervise and the names of the physicians who participated or condoned the practice. *Id.* The plaintiff estimated that he personally performed one thousand procedures without such supervision. *Id.* 686 F.Supp.2d at 265. The Court reasoned that while the allegations, taken as true, established that the defendant routinely failed to ensure the presence of a physician at certain procedures and fabricated patient reports to falsify such a presence, the plaintiff's complaint was still subject to dismissal because the plaintiff failed to allege that bills for those procedures were ever presented to Medicare/Medicaid for reimbursement. *Id.* The plaintiff failed to identify any particular case where a fraudulent bill was presented or any factual basis to conclude that he personally observed or had reason to know that a fraudulent claim was submitted. *Johnson*, 686 F.Supp.2d at 268. The court held, even if viewed under a "relaxed" standard, the plaintiff failed to plead that any fraudulent claims were presented to Medicare. *Id.*

B. Application

Plaintiff vaguely alleges that from 2004 to present, defendant submitted fraudulent claims for payment based upon false certifications that defendant was in compliance with Medicare rules and regulations for quality of care. In the second amended complaint, plaintiff asserts, *inter alia*:

> Upon information and belief, DCI has submitted thousands of claims for reimbursement of Medicare claims. (Sec. Am. Compl. ¶ 40).
>
> . . . DCI's UDC facility routinely and systematically violated the conditions of Part 494. (*Id.* at ¶ 42).
>
> Any claim that DCI submitted for Medicare reimbursement during the period of time that it was not in compliance with the Part 405 and 494 regulations (at the very least the time that relator was working there, from August 2007 through October 2008) was a false claim, because DCI falsely represented that it was in compliance with regulatory criteria. (*Id.* at ¶ 45).
>
> DCI obtained reimbursement from the federal government upon its false representations that it was in compliance with regulatory criteria. (*Id.* at ¶ 46).

Plaintiff also provided 16 examples of alleged violations of patient safety and summarized those allegations as follows[9]:

> UDC systematically violated proper medical procedures, New York State requirements for limiting the practice of nursing to registered and licensed nurses, and also engage in a variety of basically unsafe practices. (*Id.* at ¶ 142).
>
> Most of these practices were the result of inadequate staffing: because DCI refused to provide an adequate number of RNs and LPNs, and permitted PCTs to perform the work of the LPNs and RNs and LPNs to perform the work of RNs. (*Id.* at ¶ 143).
>
> As a result, patients were placed at risk because of the lack of proper staffing, medical records were falsified, and patients were

[9] The 16 examples were set forth in "Background", *supra*.

> subjected to the risk of having their dialysis treatment compromised by exposure to contaminated medical supplies. (*Id.* at ¶ 144).
>
> DCI's claims for payment for dialysis performed at UDC under the Medicare, Medicaid and Veterans Administration programs are false claims because: 1) DCI is falsely certifying that it is in compliance with the applicable regulations for dialysis facilities and 2) DCI knows the United States would not pay these claims if it was aware of the poor quality of care that DCI is providing to patients. (*Id.* at ¶ 165).

Plaintiff's complaint contains imprecise references to "routine[] and systematic[]" violations of Medicare regulations and while he claims that defendant, "submitted thousands of claims for reimbursement of Medicare claims", he fails to identify even one, specific fraudulent claim. Plaintiff did not annex copies of any bills, claims or other documents to the complaint, amended complaint or second amended complaint. Moreover, plaintiff failed to provide details regarding any fraudulent claims including when the purportedly false claims were presented, which employee of defendant submitted the claim or the amount of said claim. Plaintiff provided the approximate year of alleged quality care violations but did not provide specific dates, the names of defendant's employees who treated the patients, what services were provided or how and by whom false claims were generated as a result of those services. Even if the Court assumes plaintiff's allegations of compromised patient care to be true, plaintiff has not identified a single bill submitted in relation to any of the examples outlined in the second amended complaint. Despite three attempts to articulate his allegations, plaintiff fails to cite to a single fraudulent record or billing submission. *Cf. Winslow*, 2007 WL 1584197, at *7 (the plaintiff identified the alleged false statements, when and where they were made and attached a list of every shipment that he claimed was incorrectly classified with the port of entry).

Plaintiff argues that even though no "specific claim" for payment is identified, the complaint gives defendant adequate notice of the allegations. Plaintiff summarily asserts that, "any bill submitted to the government is . . . a fraudulent claim". This is exactly the type of vague and generalized allegation that is impermissible under Rule 9(b). Plaintiff's allegations are founded, "upon information and belief" rather than personal knowledge of any fraudulently submitted claims. In this regard, plaintiff argues that he is entitled to a relaxed standard of pleading as he was a registered nurse and not working in DCI's billing or accounting department. Although it is permissible to make an allegation "upon information and belief" in a complaint alleging fraud so long as the plaintiff also alleges that the information is "peculiarly within the opposing party's knowledge," and offers "a statement of the facts upon which the belief is based", *DiVittorio*, 822 F.2d at 1247, plaintiff does not claim that the particulars of the alleged fraud is within defendant's knowledge. Thus this exception does not apply. Even assuming plaintiff was entitled to the benefit of a relaxed pleading standard, the facts alleged still do not support a "strong inference of fraud". Accordingly, all of plaintiff's claims based upon the federal FCA and New York State laws are dismissed for lack of particularity under Rule 9(b).

V. MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

In the alternative, defendant argues that plaintiff's claims are subject to dismissal for failure to state a claim pursuant to Rule 12(b)(6). Despite this Court's conclusion in Part IV, an analysis of this argument is necessary with respect to the future course of this litigation. If, upon review of the second amended complaint, the Court determines that plaintiff cannot overcome this motion and provide facts sufficient to state a claim, the action will be dismissed with prejudice. Conversely, if plaintiff satisfies his burden at this stage of the litigation, the Court may exercise

its discretion and afford plaintiff a third opportunity to replead to conform with the requirements of Fed. R. Civ. P. 9(b).

A. Legal Standard

1. Rule 12(b)(6)

In addressing defendant's motion to dismiss, the Court accepts as true all of the factual allegations in the second amended complaint and draws inferences from those allegations in the light most favorable to the plaintiff. *See Albright v. Oliver*, 510 U.S. 266, 268 (1994); *McEvoy v. Spencer*, 124 F.3d 92, 95 (2d Cir. 1997). Dismissal is proper only where "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Valmonte v. Bane*, 18 F.3d 992, 998 (2d Cir. 1994). "[T]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims". *Todd v. Exxon Corp.*, 275 F.3d 191, 198 (2d Cir. 2001). It is well settled that the Court may not look to evidence outside the pleadings in deciding a Rule 12(b)(6) motion to dismiss for failure to state a claim. *Kramer v. Time Warner, Inc.*, 937 F.2d 767, 773 (2d Cir. 1991) ("In considering a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), a district court must limit itself to facts stated in the complaint or in documents attached to the complaint as exhibits or incorporated in the complaint by reference."). A court may consider "any written instrument attached to [the complaint] as an exhibit or any statements or documents incorporated in it by reference". *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991).

B. Liability under FCA

To assert a cause of action pursuant to § 3729(a)(1)(B), a plaintiff must allege that: (1) defendant made, or caused to be made, a false or fraudulent record or statement, (2) defendant

knew it to be false or fraudulent, and (3) it was material to a claim. *U.S. ex rel. Perez v. Beth Israel Med. Ctr*, 2010 WL 3543457, at *4 (S.D.N.Y. 2010). "The Act expansively defines the term 'claim' to cover 'any request or demand, whether under a contract or otherwise, for money or property . . . if the United States Government provides any portion of the money or property which is requested or demanded'". *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001) (citing 31 U.S.C. § 3729(c)). Generally, there are two types of FCA violations, legally false claims (a claim provided in violation of a contract, specification, regulation or statute) and factually false claims (a claim for goods or services not provided). *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir.2008); *see also Mikes*, 274 F.3d at 697.

1. Legally False Certification Theory

The legally false certification theory of liability is predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term. *Mikes*, 274 F.3d at 697 (citing Robert Fabrikant & Glenn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 Ala. L.Rev. 105, 111-12 (1999)). The Second Circuit follows the majority view and has held that a claim is only legally false when the party certifies compliance with a statute that is a condition to governmental payment. *Id.* Legally false certification may be express or implied.

a. Express False Certification

Under the express false certification theory of liability, a plaintiff may bring an FCA action premised on, "a claim that falsely certifies compliance with a particular statute or regulation", where compliance is a prerequisite to payment. *Mikes*, 274 F.3d at 695. No specific form of "certification" is required, so long as the statement of compliance is knowingly false when it was made. *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 707 F.Supp.2d 123, 133 (D. Mass.

2010). Here, plaintiff's express false certification allegations are based upon Form CMS 855A (the Medicare enrollment form). Plaintiff argues that Form CMS 855A, signed by defendant, makes compliance with Medicare regulations a precondition of government payment. Plaintiff further claims that by executing this form, defendant expressly certified it would comply with all conditions of participation as a prerequisite to Medicare payment. Plaintiff cites to Paragraph 3 of Section 15 - Certification Statement which reads, in relevant part:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all application conditions of participation in Medicare.

Defendant argues that the Medicare enrollment application is not a claim for payment. Moreover, defendant asserts that the form is merely an agreement to comply in the future with all applicable laws and regulations.

Two recent district court cases are instructive on this issue. In *U.S. ex rel. Kennedy v. Aventis Pharm., Inc*., 610 F.Supp.2d 938, 946 (N.D. Ill. 2009), the relator alleged that the defendant executed a certification attesting that it understood, "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare." The Court held that the relator failed to identify any particular claim that involved goods or services obtained via a kickback. *Id*. Thus, the Court held that the plaintiff could not

assert a claim under this theory unless he identifies an express false certification of compliance with the anti-kickback statute in connection with a Medicare claim. *Id*.

In the case of *U.S. ex rel. Westmoreland v. Amgen, Inc*., 707 F.Supp.2d 123 (D. Mass. 2010), the plaintiff and defendant presented identical arguments in an express certification claim based upon the very same Medicare enrollment form, CMS 855A.[10] The defendant argued that as a provider, they were required to complete the form in order to participate in the Medicare program, thus, it did not qualify as an "express certification". The defendant, relying upon *Kennedy*, 610 F.Supp.2d at 938, asserted that the language in the form was, "only an agreement to comply with the anti-kickback statute in the future and not an express certification that one has complied with the anti-kickback statute". *Id*. at 134.

The Court rejected defendant's argument and held, " there is no reason why such an explicit certification of future compliance cannot be the basis of False Claims Act liability if the provider makes such a certification knowing that it will violate the statute, and later submits claims which are not in compliance with the statute". *Id*. at 135. Nevertheless, the Court held that the plaintiff's claim failed because:

> the problem here is not necessarily the "forward-looking" language of the certification or that the certification is contained in an enrollment form instead of a claim form, but rather that the Plaintiffs have not alleged that providers expressly made such statements knowing their falsity. The Plaintiffs do not allege that when the providers signed the enrollment forms, they knew that they would be accepting kickbacks from the Defendants in violation of the anti-kickback statute. Without such pleading, there can be no "false claim." Therefore, Relator's Complaint fails to state a legally false claim under the express certification theory.

[10] In the *Westmoreland* decision, the Court cited the applicable language of the enrollment form in Footnote 3. The language that the plaintiff relied upon is identical to the language cited in Section 15, paragraph 3 of Form 855A herein.

Id. at 136.

Here, plaintiff relies upon the identical language in the same enrollment form as a basis for his express false certification claim. Plaintiff alleges that by executing the form, defendant certified that it would comply with objective standards of medical care. This Court finds the analysis in *Westmoreland* to be persuasive and, as plaintiff has failed to cite to any holding to the contrary, this Court agrees and adopts the reasoning of the Massachusetts district court. As discussed in Part IV(B), plaintiff has failed to identify any fraudulent claim for payment by defendant to the Government. Moreover, plaintiff failed to allege that defendants knew, when they signed the form, that they would be accepting payment in violation of the anti-kick back statute. Accordingly, plaintiff's second amended complaint fails to state a claim under the express false certification theory of liability.

b. Implied False Certification

"An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment". *Mikes*, 274 F.3d at 699. "Where a contractor participates in a certain government program in order to perform the services for which payments are eventually made-in this case, Medicare-courts are careful to distinguish between conditions of program participation and conditions of payment." *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc*., 543 F.3d 1211, 1220 (10th Cir. 2008) (citations omitted). "Conditions of participation, as well as a provider's certification that it has complied with those conditions, are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program." *Id.* "Conditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment." *Id.*

The Second Circuit case of *Mikes* is the leading authority on the issue of implied false certification and its holding has been followed and adopted by several other Circuit Courts.[11] The Second Circuit discussed the theory of implied certification and its applicability in the health care context. The Court reasoned:

> . . . the False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations-but rather only those regulations that are a precondition to payment-and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach. Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that "the regulation of health and safety matters is primarily, and historically, a matter of local concern."

Mikes, 274 F.3d at 699-700 (citations omitted). The Court further noted, "permitting *qui tam* plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff". *Id.* at 700. (citation omitted).

Accordingly, the Court limited the use of implied certification by relators against medical providers holding:

> . . . implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid. Liability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing-as that

[11] *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993 (9th Cir. 2010); *U.S. ex rel. Conner v. Salina Regional Health Ctr., Inc.*,543 F.3d 1211 (10th Cir. 2008); *U.S. ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601 (7th Cir. 2005); *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005); *U.S. ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432 (3d Cir. 2004); *U.S. ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409 (6th Cir. 2002).

> term is defined by the Act,[ ] that payment expressly is precluded because of some noncompliance by the defendant.

Id. (internal citations omitted).

The Court applied this reasoning to the plaintiff's claim that the defendants' compliance with §§ 1395y(a)(1)(A) and 1320c-5(a) of the Medicare statute was a precondition to a request for federal funds. The plaintiff argued that the defendants submitted an HCFA-1500 claim forms and therefore attested, by implication, to compliance with that statute.[12] *Mikes*, 274 F.3d at 700-701. With regard to § 1395y(a)(1)(A), while the section expressly precluded the government from reimbursing a Medicare provider who fails to comply with its terms, the Court held the plaintiff could not rely upon the claim that the defendants' performance of medical services was *qualitatively* deficient as a basis for implied false certification under § 1395y(a)(1)(A). *Id.* (emphasis supplied).

Conversely, § 1320c-5(a) did not explicitly condition payment upon compliance with its terms. Rather, that section acted prospectively, setting forth obligations for a provider to be

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[12] Section 1395y(a)(1)(A) provides:

> "no payment may be made under [the Medicare statute] for any expenses incurred for items or services which ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

42 U.S.C. § 1395y(a)(1)(A).

The applicable portion of § 1320c-5(a) provides:

> It shall be the obligation of any health care practitioner ... who provides health care services for which payment may be made ... to assure, to the extent of his authority that services or items ordered or provided by such practitioner ...
> (1) will be provided economically and only when, and to the extent, medically necessary;
> (2) **will be of a quality which meets professionally recognized standards of health care**; and
> (3) will be supported by evidence of medical necessity and quality ... as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

42 U.S.C. § 1320c-5(a) (emphasis added).

eligible to participate in the Medicare program. *Id.* at 701. The Court held that 1320c-5(a) established conditions of participation, not prerequisites to receiving reimbursement. *Id.*

The Court found support for the holding in the structure of the entire statute, specifically, Section 1320c-5(b). That section provided:

> If a peer review organization determines that a provider has "failed in a substantial number of cases" to comply with the requirements of § 1320c-5(a) or that the provider has "grossly and flagrantly violated" the section, the organization may-after reasonable notice and an opportunity for corrective action-recommend sanctions.

Mikes, 274 F.3d at 702. The Court held:

> The fact that § 1320c-5(b) permits sanctions for a failure to maintain an appropriate standard of care only where a dereliction occurred in "a substantial number of cases" or a violation was especially "gross[ ] and flagrant[ ]" makes it evident that the section is directed at the provider's continued eligibility in the Medicare program, rather than any individual incident of noncompliance. This conclusion is reinforced by the ultimate sanction provided by § 1320c-5(b)(1): exclusion of the provider from Medicare eligibility. Further, the section explicitly provides that the Secretary may authorize an alternate remedy-repayment of the cost of the noncompliant service to the United States-"as a condition to the continued eligibility" of the health care provider in the Medicare program. 42 U.S.C. § 1320c-5(b)(3). Accordingly, § 1320c-5(a) is quite plainly a condition of participation in the Medicare program.
>
> Since § 1320c-5(a) does not expressly condition payment on compliance with its terms, defendants' certifications on the HCFA-1500 forms are not legally false. Consequently, defendants did not submit impliedly false claims by requesting reimbursement for spirometry tests that allegedly were not performed according to the recognized standards of health care.

Id.

The *Mikes* holding was discussed and adopted in two cases with strikingly similar factual patterns: *U.S. ex rel. Lacy v. New Horizons, Inc*., 2008 WL 4415648, at *4-5 (W.D. Okla. 2008) and *U.S. ex rel. Landers v. Baptist Memorial Health Care Corp*., 525 F.Supp.2d 972 (W.D. Tenn.

2007). In *Lacy*, the plaintiff alleged that the defendant failed to comply with statutes involving care for patients at Intermediate Care Facilities for the Mentally Retarded. The plaintiff argued that due to the defendant's failure to comply with 42 C.F.R. § 483.410[13], the defendant's submission of reports certifying compliance with statutory requirements represented an implied false certification in violation of the FCA. *Id.* The court held:

> The certifications upon which plaintiff seeks to rely do not involve compliance with statutes or regulations as a condition to the government payment. Her allegations related to program compliance primarily revolve around 42 C.F.R. Ch. IV, Subch. G, Pt. 483, Subpt. I, "Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded." 42 C.F.R. § 483.410 et seq. These provisions delineate specific requirements that [] facilities which participate in federally funded programs must meet. Their violation may result in termination of a facility's participation in the program, should the appropriate agency so determine, but they do not constitute conditions to government payments within the meaning of *Mikes*, *Conner* and the other cases referenced above which have considered the issue in a health care context.

Id. at *5.

In *U.S. ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F.Supp.2d 972 (W.D. Tenn. 2007), the plaintiff argued that the defendants certified that they complied with 42 C.F.R. § 482 *et seq.* (conditions of participation for hospitals) but failed to follow the Conditions of Participation for, *inter alia*, failing to provide a sanitary environment. The Court held that the plaintiff failed to demonstrate that the defendants' alleged non-compliance with Medicare's

[13] Section 483.410 is entitled Condition of participation: Governing body and management. Section 483.1(b) defines the scope of the section as follows:

> The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a SNF in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid..

Condition of Participation imposed liability under an express or implied theory. *Id.* at 978. The court held that conditions of participation, "are quality care standards directed towards an entity's continued ability to participate in the Medicare program rather than a prerequisite to a particular payment. *Id.* The court further noted,

> Although Defendants' alleged non-compliance with Conditions of Participation may lead to prospective corrective action or even termination, Plaintiff has not presented any evidence that Defendants would have been ineligible to receive payment of its Medicare claims during a potential period of non-compliance.

Id. at 979.

Here, plaintiff alleges that defendant is liable for impliedly certifying compliance with the conditions of participation set forth in 42 C.F.R. § 494 *et seq*. Plaintiff claims that compliance with that section is mandated because, "there is nothing in Part 494 that would permit a medical provider to assert a claim for money services rendered in violation of regulatory requirements". Plaintiff further argues that 42 C.F.R. §§ 488.604 and 488.606 mandate that explicit compliance with 42 C.F.R § 494 is a precondition for payment. Defendant disagrees, relies upon *Mikes* and asserts that § 494 is a condition for coverage.

Section 494 of Title 42 of the Code of Federal Regulations is entitled, "Conditions for Coverage for End-Stage Renal Disease Facilities". The language in the statute clearly defines the scope of the provision:

> Scope. The provisions of this part establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered.

42 CFR § 494.1(b).

Section 488 is entitled, "Survey, Certification, and Enforcement Procedures. Subpart H is Termination of Medicare Coverage and Alternative Sanctions for ESRD Facilities. The relevant portions of the section provides:

§ 488.604 Termination of Medicare coverage.

> (a) Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.
>
> (c) If termination of coverage is based on failure to meet any of the other conditions specified in part 494 of this chapter, coverage will not be reinstated until CMS finds that the reason for termination has been removed and there is reasonable assurance that it will not recur.

§ 488.606 Alternative sanctions.

> (a) Basis for application of alternative sanctions. CMS may, as an alternative to termination of Medicare coverage, impose one of the sanctions specified in paragraph (b) of this section if CMS finds that–
>
> (1) The supplier fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass the supplier's geographic area; and
>
> (2) This failure does not jeopardize patient health and safety.
>
> (b) Alternative sanctions. The alternative sanctions that CMS may apply in the circumstances specified in paragraph (a) of this section include the following:
>
> (1) Denial of payment for services furnished to patients first accepted for care after the effective date of the sanction as specified in the sanction notice.
>
> (2) Reduction of payments, for all ESRD services furnished by the supplier, by 20 percent for each 30-day period after the effective date of the sanction.
>
> (3) Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries.

> (c) Duration of alternative sanction. An alternative sanction remains in effect until CMS finds that the supplier is in substantial compliance with the requirement to cooperate in the network plans and goals, or terminates coverage of the supplier's services for lack of compliance.

Upon review of the facts, statutes and caselaw, this Court finds no reason to deviate from Second Circuit precedent and the holding in *Mikes*. The language in 42 C.F.R. § 494 clearly establishes a condition of participation, not prerequisites to receiving reimbursement from the government. While the scope of § 494 is clearly defined in § 494.1, the text of the remaining sections, 494.20 through 494.180, further support the conclusion that the regulations provide conditions of participation, not payment. Sections 494.20 through 494.180 apply to "conditions" relating to, *inter alia*: infection control, water and dialysate quality, reuse of hemodialyzers, care at home, quality assessment, physical environment, patients rights, patient assessment, personnel qualifications and medical records. In order to participate in the Medicare program, defendant, a dialysis center providing treatment for ESRD, must meet and adhere to these "conditions" as standards for the quality of care. *See Landers*, 525 F.Supp.2d at 978 ("conditions of participation" are quality of care standards directed towards an entity's continued ability to participate in the Medicare program, not a prerequisite for a particular payment).

Further support for the conclusion that § 494 clearly establishes a condition of participation is found in § 488.604 which specifically provides for the "ultimate sanction" of termination if the defendant is non-compliant and § 488.606 which provides for alternate sanctions so that defendant may continue to receive Medicare payments during a period of non-compliance. These provisions provide redress for violations of § 494 including possible expulsion from the program but they do not address, discuss or even reference government payments. Indeed, § 488.606 permits a provider to receive Medicare payments during a period of

non-compliance with 42 CFR § 494 *et seq*. Moreover, alternative sanctions remain in effect until the provider substantially complies with the requirements or the government terminates coverage of the supplier's services for lack of compliance. Regulations that, "permit the sanction of terminating supplier eligibility make it evident that [violations of quality of care standards] is directed at the provider's continued eligibility in the Medicare program, rather than any individual incident of noncompliance". *See U.S. ex rel. Cooper v. Gentiva Health Servs., Inc*., 2003 WL 22495607, at *8 (W.D. Pa. 2003) (Section 424.57 provided that the proper redress for violations of the standards was not the denial of payment, but the revocation of the supplier's billing privileges).

Plaintiff concedes that § 494 does not expressly condition payment on compliance with its terms, but argues, "nothing in Part 494 would permit a medical provider to assert a claim for money services rendered in violation of regulatory requirements". Plaintiff has no authority to support that premise. In opposition to defendant's motion, plaintiff cites to two district court cases: *U.S. ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Oklahoma, Inc*., 945 F.Supp. 1485 (W.D.Okla.1996) and *U.S. v. NHC Healthcare Corp*., 115 F.Supp.2d 1149 (W.D. Mo. 2000). Plaintiff's reliance on the holdings in these cases is misplaced. The holding in *Aranda* was explicitly rejected by the lower court in *Mikes*:

> [plaintiff] relies on the only case that finds that a defendant's non-compliance with § 1320c-5(a) was actionable as an implied false certification under the FCA. *See United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc*., 945 F.Supp. 1485 (W.D.Okla.1996). Because I find persuasive the [Seventh Circuit's] determination that a finding of falsity under the FCA is precluded where payment has not been conditioned upon statutory compliance, and that a contrary result would impermissibly broaden the scope of the FCA, I decline to follow *Aranda*.

Mikes, 84 F.Supp.2d 427, 436 (S.D.N.Y. 1999).

Similarly, the conclusions in both *NHC Healthcare Corp*. and *Aranda* have not been adopted by any appellate court:

> Some courts have held that submitting Medicare or Medicaid claims for services that fail to meet the relevant statutory standard of care can constitute actionable fraud under the FCA. *See United States v. NHC Healthcare Corp*., 115 F.Supp.2d 1149 (W.D.Mo.2000); *United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc*., 945 F.Supp. 1485 (W.D.Okla.1996). However, these questionable holdings have not been adopted by the Ninth Circuit or any other appellate court. The prevailing law is that "regulatory violations do not give rise to a viable FCA action" unless government payment is expressly conditioned on a false certification of regulatory compliance. Swan has introduced no evidence to demonstrate that Covenant Care certified compliance with the applicable Medicare regulations as prerequisite to receiving federal payment.

U.S. ex rel. Swan v. Covenant Care, Inc., 279 F.Supp.2d 1212, 1221 (E.D.Cal. 2002) (internal citations omitted).

Here, defendant's alleged non-compliance with the Conditions of Participation set forth in § 494 *et seq*. does not impose liability under an implied false certification theory. The Court adheres to the majority view established by *Mikes* and followed almost universally throughout the Circuits and holds that plaintiff's second amended complaint fails to state a cause of action for fraud under the theory of implied false certification.

2. Factually False/Worthless Services Claim

Factually false Medicare claims "involve[ ] an incorrect description of goods or services provided or a request for reimbursement for services never provided." *Mikes*, 274 F.3d at 697. Allegations of "worthless services" are a derivative of a factually false claim. *Id.* at 703 ("worthless services claims assert that the knowing request of federal reimbursement for a procedure with no medical value violates the Act irrespective of any certification"). Plaintiff addresses the "worthless services" theory for the first time in his opposition to defendant's motion

for dismissal. Plaintiff argues that defendant may be liable for providing care which is so poor that the government would not, had it been aware of the circumstances, have paid for the care. Plaintiff claims that the OMIG audit report supports his position.

"[A] worthless services claim asserts that the knowing request of federal reimbursement for a procedure with no medical value violates the Act irrespective of any certification". *Mikes*, 274 F.3d at 702. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all. *Id.* at 703. To establish a "worthless services" claim, the plaintiff must establish that defendants knowingly submitted a claim for reimbursement for worthless services. *Id.* (citing *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996)) (knowing requires an element of intent of what is known to be false as opposed to negligence or innocent mistake); *see also U.S. ex rel. Lee v. Smithkline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001) (knowingly billing for worthless services or recklessly doing so with deliberate ignorance is actionable under § 3729).

Here, the second amended complaint contains no allegations regarding worthless services and plaintiff does not seek to replead this issue. Plaintiff presents arguments and claims supporting this theory for the first time in his brief in opposition to defendant's motion. Because these claims were not asserted in the complaint, amended complaint or second amended complaint, plaintiff cannot incorporate these claims by reference. *See Georgandellis v. Holzer Clinic, Inc.*, 2009 WL 1585772, at *16 (S.D.Ohio 2009). Accordingly, the Court must decide this issue based upon the claims in the second amended complaint.

Plaintiff does not allege that defendant failed to provide **any** services to their patients. Rather, plaintiff challenges the quality of care arguing that defendant's services did not conform with the guidelines set forth in 42 C.F.R. § 494. This allegation is not the "equivalent of no

performance at all" and thus, does not fit within the worthless services category. *See Mikes*, at 703; *see also Swan*, 279 F.Supp.2d at 1221 (the plaintiff challenged the defendant's level of care and the amount of services the patients received as a result of under-staffing at the defendant's facility); *see also Sweeney v. ManorCare Health Servs., Inc*., 2005 WL 4030950, at *6 (W.D. Wash. 2005) (it would be impossible to determine whether particular services provided were worthless without finding that the care as a whole was worthless).

Accordingly, defendant's motion to dismiss plaintiff's worthless services claim for failure to state a cause of action is dismissed.

VI. NEW YORK FALSE CLAIMS ACT

The N.Y. False Claims Act is, "closely modeled on the federal FCA". Accordingly, plaintiff's claims under the state statute are subject to dismissal for the same reasons as plaintiff's federal FCA claims. *See Perez*, 2010 WL 3543457, at *8.

VII. DISMISSAL WITH PREJUDICE

While plaintiff has not sought leave to file another amended complaint, the Court must address the issue of whether plaintiff's allegations merit a fourth opportunity to plead fraud with particularity. Dismissal with prejudice is appropriate under Rule 9(b) where there is a "good reason to deny the motion", including "when such leave would be futile". *Acito v. IMCERA Group, Inc*., 47 F.3d 47, 54-55 (2d Cir.1995) (citing Fed.R.Civ.P. 15(a)). While it is true that dismissals for failure to comply with Rule 9(b) are often without prejudice, plaintiff must offer a reason or suggestion as to how he may provide details to the claims made against defendant before leave will be granted. *U.S. ex rel. Poteet v. Bahler Med., Inc*., 619 F.3d 104, 115 -116 (1st Cir. 2010). Most courts do not permit parties to conduct discovery in order to satisfy the

requirements of Rule 9(b). *U.S. ex rel. Polansky v. Pfizer, Inc*., 2009 WL 1456582, at *10 (E.D.N.Y. 2009) (citations omitted). In *Polansky*, the court reasoned:

> The reluctance of courts to permit *qui tam* relators to use discovery to meet the requirements of Rule 9(b) reflects, in part, a concern that a qui tam plaintiff, who has suffered no injury in fact, may be particularly likely to file suit as a pretext to uncover unknown wrongs. When a plaintiff does not specifically plead the minimum elements of [his] allegation, it enables [the plaintiff] to learn the complaint's bare essentials through discovery and may needlessly harm a defendant['s] goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are [sic] baseless allegations used to extract settlements. Moreover, allowing a *qui tam* relator to amend his or her complaint after conducting discovery would mean that "the government will have been compelled to decide whether or not to intervene absent complete information about the relator's cause of action." Such an approach is inconsistent with the relator's procedural obligations under the FCA and with the FCA's protections for the government, the real party in interest in a *qui tam* action.

Id. (internal citations omitted).

Here, plaintiff has already filed three complaints and failed to comply with the 12(b)(6) pleading standards and the stricter requirements of 9(b). An analysis of the second amended complaint and the legal theories upon which it is based establishes that the shortcomings could not be cured by amendment. *See Masters v. GlaxoSmithKline*, 271 F.App'x. 46, 51 (2d Cir. 2008). Plaintiff's employment with defendant ended over two years ago. Thus, it is, "highly unlikely that he would be able to plead fraud with any particularity even of he was given another opportunity to amend". *See Smith*, 2007 WL 2142312, at *7. In light of plaintiff's prior opportunities to amend, the Clerk shall enter final judgment of dismissal with prejudice. *See Perez*, 2010 WL 3543457, at *8.

CONCLUSION

Based upon the foregoing, it is hereby

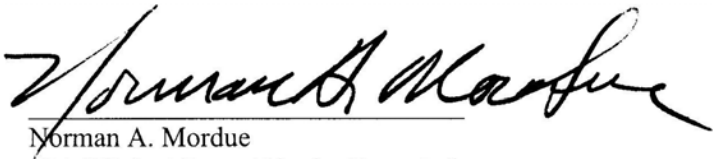
ORDERED that plaintiff's cross motion (Dkt. No. 30) for leave to file the second amended complaint is **GRANTED**. Plaintiff's proposed Second Amended Complaint is deemed filed; it is further

ORDERED that defendant's motion to dismiss the second amended complaint based upon Fed. R. Civ. P. 12(b)(1) and 12(h)(3) (Dkt. No. 34) is **DENIED**; it is further

ORDERED that for the reasons provided above, defendant's motion to dismiss the second amended complaint based upon Fed. R. Civ. P. 9(b) and Fed. R. Civ. P. 12(b)(6) (Dkt. No. 27) is **GRANTED** and the second amended complaint is dismissed with prejudice.

IT IS SO ORDERED.

Date: January 19, 2011



Norman A. Mordue
Chief United States District Court Judge